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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application of: Gauch et al.
Serial No.: 09/536,735
Filed: March 28, 2000
Entitled: ISOLATION OF NUCLEIC
ACIDS ON SURFACES

ART UNIT: 1655

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Assistant Commissioner for Patents
Washington, D.C. 20231

**PRELIMINARY AMENDMENT AND
RESPONSE TO RESTRICTION REQUIREMENT**

Sir:

This paper is filed in response to the Office Action (Paper No. 5), dated January 24, 2001, in the above-identified application. Pursuant to 37 C.F.R. § 1.136(a), a Petition for a two-month extension in time is submitted concurrently herewith along with a check in payment of the fee under 37 C.F.R. § 1.17(a)(2).

Please amend the application as indicated below.

IN THE CLAIMS

Please cancel Claims ~~21-36~~, ~~96-111~~, and ~~117-120~~, without prejudice.

Please amend Claims 37, 38, 40, 41, 42, 43, 46, 49, 54, 58, 59, 64, 66, 69, 70, 75, and 76, and add new Claims 121, 122, 123, and 124, as indicated below and on a separate sheet pursuant to 37 C.F.R. § 1.121(c)(1)(i). A version of the amended and new claims with markings on a separate sheet pursuant to 37 C.F.R. § 1.121(c)(1)(ii) is also enclosed herewith at Tab A, and a complete set of pending Claims 1-20, 37-95, 112-116, and 121-124, as amended herein, is provided pursuant to 37 C.F.R. § 1.121(c)(3) at Tab B.

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C1
37. (amended) The process according to any one of Claims 9 or 14, characterized in that the sample is introduced onto the top of the surface.

38. (amended) A process according to any one of Claims 1, 9, or 19, characterized in that the immobilized nucleic acids are subjected to a washing step which takes place with at least one washing buffer after the immobilization and before any release steps.

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C6
40. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that an aqueous salt or buffer solution is used to release the nucleic acids.

41. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that water is used to release the nucleic acids.

42. (amended) The process according to one of Claims 1, 9, or 14, characterized in that the application and immobilization of the nucleic acids includes the following steps:
mixing at least one nucleic acid-containing sample with an immobilization buffer;
applying said at least one nucleic acid-containing sample with the immobilization buffer to the surface or membrane; and
passing the liquid components through the surface in essentially the same direction they were added.

43. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that at least one of the steps is carried out by an automatic device, in a fully automatic manner.

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C7
46. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that aqueous salt solutions of metal and/or ammonium cations with mineral acids are used to immobilize the nucleic acids.

49. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that aqueous solutions of salts of mono or polybasic or polyfunctional organic acids with alkaline or alkaline-earth metals are used to immobilize the nucleic acids.

54. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that hydroxy-functional compounds of aliphatic or acyclic saturated or unsaturated hydrocarbons are used for the immobilization of the nucleic acids.

58. (amended) The process according to any one of Claims 1, 9, or 19, characterized in that a phenol or polyphenol is used for the immobilization of the nucleic acids.

59. (amended) The process according to any one of Claims 1, 9, or 19, wherein at least one chaotropic agent is used for the immobilization of the nucleic acids.

64. (amended) The process according to Claim 61, wherein the chaotropic agent is selected from an aqueous solution of one or more of sodium perchlorate, guanidinium hydrochloride, guanidinium isothiocyanate, sodium iodide and potassium iodide.

66. (amended) The process according to any one of Claims 9, 14, or 19, characterized in that the surface is a membrane.

69. (amended) The process according to Claim 67, characterized in that the membrane is a hydrophilic membrane with a hydrophobic surface.

70. (amended) The process according to Claim 67, characterized in that the membrane is made of nylon, a polysulfone, polyethersulfone, polycarbonate, polypropylene, polyacrylate, acrylic copolymer, polyurethane, polyamide, polyvinylchloride, polyfluorocarbonate, poly-tetrafluoro-ethylene, polyvinylidene fluoride, polyethylene-tetrafluoro-ethylene-copolymerisate, a polyethylene-chlorotrifluoro-ethylene-copolymerisate, cellulose acetate, nitrocellulose, polybenzimidazole, polyimide, polyacrylnitrile, polyacrylnitrile-copolymer, cellulose-mix ester, cellulose nitrate, or polyphenylene sulfide.

Sub 7
G10
75. (amended) The process according to any one of Claims 9, 14, or 19, characterized in that the membrane has a pore diameter of 0.001 to 50 micrometer.

76. (amended) The process according to any one of Claims 9, 14, or 19, characterized in that the surface is a hydrophobic fleece.

121. (new) The process according to Claim 62, wherein the chaotropic agent is selected from an aqueous solution of one or more of sodium perchlorate, guanidinium hydrochloride, guanidinium isothiocyanate, sodium iodide and potassium iodide.

122. (new) The process according to Claim 63, wherein the chaotropic agent is selected from an aqueous solution of one or more of sodium perchlorate, guanidinium hydrochloride, guanidinium isothiocyanate, sodium iodide and potassium iodide.

G11
123. (new) The process according to Claim 68, characterized in that the membrane is a hydrophilic membrane with a hydrophobic surface.

124. (new) The process according to Claim 68, characterized in that the membrane is made of nylon, a polysulfone, polyethersulfone, polycarbonate, polypropylene, polyacrylate, acrylic copolymer, polyurethane, polyamide, polyvinylchloride, polyfluorocarbonate, poly-tetrafluoro-ethylene, polyvinylidene fluoride, polyethylene-tetrafluoro-ethylene-copolymerisate, a polyethylene-chlorotrifluoro-ethylene-copolymerisate, cellulose acetate, nitrocellulose, polybenzimidazole, polyimide, polyacrylnitrile, polyacrylnitrile-copolymer, cellulose-mix ester, cellulose nitrate, or polyphenylene sulfide.

REMARKS

In the Office Action, the Examiner restricted original Claims 1-120 into the following five Groups:

- I. Claims 1-20, 38-64, 73-95, and 112-116, as drawn to a process for isolating nucleic acid;
- II. Claims 21-28, 38-72, 75, and 76, as drawn to a process for performing a nucleic acid amplification reaction;
- III. Claims 29, 37-72, 75, and 76, as drawn to a process for performing chemical reactions on nucleic acids;
- IV. Claims 30-39 and 42-64, as drawn to a process for the analysis of nucleic acid in an isolation device; and
- V. Claims directed to apparatuses and kits consisting of: Claims 96 and 97, as drawn to an apparatus; Claims 98-109, as drawn to an isolation device; Claims 110 and 111, as drawn to an isolation device adapted for the isolation of nucleic acids; and Claims 117-120, as drawn to a kit comprising said device.

The overlap in the above restriction Groups is due to the use of multiple dependent claims acting as the bases for other multiple dependent claims, apparently owing to use of a European style of writing claims.

Applicants elect to prosecute claims directed to a process for isolating nucleic acid, such as found in the Claims in restriction Group I.

Applicants have amended the Claims in order to eliminate multiple dependent claims serving as bases for other multiple dependent claims and to eliminate dependency on non-elected inventions. Accordingly, the amendments are made purely to set the Claims them in proper form for examination, do not add new matter, and do not touch any point of patentability.

Entry of the amendments is respectfully requested.

As the result of the amendments, the following additional Claims are now properly placed into Group I: Claims 37, 65-72, and new Claims 122-124.

In the case of Claim 37, the amendment was made to eliminate dependency to non-elected subject matter and to recite language only consistent with the dependency from Claims 9 and 14. In particular, the term "surface" is consistent with dependency from Claims 9 and 14, whereas the term "membrane" only corresponds to dependency from non-elected Claim 30.

In the case of Claim 42, the amendment not only eliminates dependency from non-elected Claims 21, 29, and 30, but also eliminates superfluous numbering of the recited steps, and copies the language specifically found and consistent with dependency from Claims 1, 9, and 14 (i.e., "applying", instead of "introduction"; see, also, p. 14, lines 25-30 of the specification).

New Claims 121 and 122, which depend from Claims 62 and 63, respectively, have been added to retain subject matter originally covered by the improper multiple dependency of original Claim 64. As amended, Claim 64 now only depends from Claim 61.

Likewise, new Claims 123 and 124, which depend from Claim 68, have been added to retain subject matter claimed in the improper multiple dependency form of original Claims 69 and 70, respectively. As amended, Claims 69 and 70 now only depend from Claim 67.

Applicants also have cancelled Claims 21-36, 96-111, and 117-120 as drawn to non-elected subject matter. Applicants reserve the right to seek patent coverage for the subject matter of the cancelled claims in one or more divisional applications.

In view of the amendments and the election and definition of a single restriction group for this application, Applicants respectfully request the Examiner's consideration and allowance of Claims 1-20, 37-95, 112-116, and 121-124.

Respectfully submitted,

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CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. § 1.8

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as First Class Mail, postage prepaid, in an envelope addressed to the Asst. Commissioner for Patents, Washington, DC 20231, on the date indicated below.

April 24, 2001

date of mailing and signature

Stephanie L. Leicht

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